

Exhibit D

1 IN THE SUPERIOR COURT OF NEW JERSEY
2 LAW DIVISION - BERGEN COUNTY
3 CIVIL ACTION
4 - - -
5 KATHRYN E. CORBET and : DOCKET NO. BER-L-14589-14 MCL
6 ERIC R. CORBET :
7 Plaintiffs, :
8 v. :
9 ETHICON, INC., ETHICON : MASTER DOCKET NO.
10 WOMEN'S HEALTH AND UROLGY, : BER-L-11575-14
11 a Division of Ethicon, :
12 Inc., GYNECARE, JOHNSON & :
13 JOHNSON, AND JOHN DOES 1-20 :
14 Defendants. :
15 - - -
16 NOVEMBER 24, 2015
17 - - -
18

19 Videotape deposition of NICOLE
20 FLEISCHMANN, M.D., taken pursuant to notice, was
21 held at the law offices of Riker Danzig Scherer
22 Hyland & Perretti, LLP, 500 Fifth Avenue, 49th
23 Floor, New York, New York 10110, commencing at 9:34
24 a.m., on the above date, before Amanda Dee
25 Maslynsky-Miller, a Certified Realtime Reporter and
Notary Public in and for the State of New York.

26 - - -
27 GOLKOW TECHNOLOGIES, INC.
28 877.370.3377 ph | 917.591.5672 fax
29 deps@golkow.com

1 standards for warnings?

2 A. I don't understand the question.

3 MS. KABBASH: Objection.

4 BY MR. SLATER:

5 Q. Did you consult any published
6 standards for what information is supposed to be
7 provided in a medical device warning like for the
8 TVTTM Retropubic?

9 A. No.

10 MS. KABBASH: Objection.

11 BY MR. SLATER:

12 Q. Did you review testimony by witnesses
13 from Ethicon who are responsible for making sure the
14 warnings are adequate, to see what standards they
15 applied, in their industry, in determining what
16 should be warned of? Did you look at those
17 standards?

18 A. I never looked at any testimony from
19 Ethicon, no.

20 Q. Did you look at any internal
21 documents from Ethicon, where they set out the
22 standards or the criteria that they applied in
23 determining what information needed to be in a
24 warning such as for the TVTTM Retropubic?

25 A. I don't believe I have, no.

1 Q. When you offer your opinions as to
2 the adequacy of the warnings, are you essentially
3 advising us what you believe would be adequate for
4 you in your medical practice, with your basic --
5 with your level of experience and what you're
6 familiar with?

7 A. Exactly, yes.

8 Q. There was some reference in your
9 report to the patient brochure or whether or not a
10 patient brochure was shown to Ms. -- Mrs. Corbet,
11 right? You talked about that a little?

12 A. Yes.

13 Q. As you sit here now, am I accurate
14 you don't know which patient brochure she actually
15 saw?

16 A. I can't say exactly. But I know the
17 brochure that was out at the time of her -- of her
18 care.

19 Q. The patient brochure that was out
20 during the time that she had her surgery in 2011, do
21 you know if that's the patient brochure that she was
22 shown during her deposition?

23 A. That's the one that she felt was
24 familiar to her, in her deposition.

25 Q. This is my question -- rephrase.

1 InterStim® to Mrs. Corbet and say, I think you
2 should have this put in your body?

3 A. Yes, he did.

4 Q. When was that?

5 A. It was after she had had surgery with
6 him.

7 Q. Do you have any knowledge as to the
8 agreement between Ethicon and Professor Olmstead and
9 his company? Do you know any of the details of that
10 interaction?

11 A. I've seen some of the records of that
12 interaction.

13 Q. Are they listed in your report?

14 A. Yes -- no, they are listed in my --
15 yeah, in my exhibit.

16 Q. Did you discuss that issue at all in
17 your report?

18 A. No.

19 Q. Have you been involved in clinical
20 studies?

21 A. No. I mean, clinical trials? No.

22 Q. You've never --

23 A. Clinical studies? Yes. But not
24 clinical trials.

25 Q. What's your distinction between a

1 your opinions?

2 A. Yes.

3 Q. Do you consider yourself to be an
4 expert with regard to the material science of the
5 mesh material in the TVTM Retropubic?

6 A. I'm not a materials expert, but I'm
7 very familiar with the mesh, as I use it on a daily
8 basis.

9 Q. Have you ever studied, from a
10 material science perspective, the mesh?

11 A. No, but it's my medium that I work
12 with.

13 MR. SLATER: Move to strike from
14 "but" forward on both of those answers, the last
15 two.

16 BY MR. SLATER:

17 Q. Have you ever participated in a study
18 of the mesh material from a histopathologic
19 standpoint, under a microscope?

20 A. No.

21 Q. With regard to the histopathology of
22 the mesh material, do you defer to those people who
23 are pathologists who study that?

24 A. Yes. But I'm not as interested in
25 the histopathology of what's going on with the mesh.

1 I'm more interested in the clinical outcomes of the
2 mesh, because I am a clinician.

3 MR. SLATER: Move to strike from
4 "but" forward.

5 BY MR. SLATER:

6 Q. Do you know -- rephrase.

7 The Nilsson studies are set forth in
8 your list here.

9 Do you know where those patients came
10 from?

11 A. The original Nilsson patients?

12 Q. The Nilsson patients --

13 A. Scandinavia.

14 Q. The Nilsson patients that he studied
15 and kept having these serial reports on?

16 A. Right. They were Scandinavian.

17 Q. Were those patients that are studied
18 in the Nilsson study, were they studied in any other
19 studies?

20 A. It was the same patients that were
21 being studied in multiple studies going forward. We
22 have 5-year data, 7-year data, 11-year data, 17-year
23 data on those same group of patients.

24 Q. This is my question: The patients
25 who are -- who are discussed in Nilsson's serial

1 A. Which pathologist is this?
2 Q. Whoever looked at the pathology that
3 was taken from the surgery by Dr. Smith.

4 That's what the hospital pathologist
5 saw, right?

6 A. The hospital pathology? Do I have
7 that report? I know that's in my --

8 MS. KABBASH: It's in your --

9 BY MR. SLATER:

10 Q. On Page 14 of your report --

11 A. Okay.

12 Q. -- it says, The pathology report
13 references skin and fibroadipose tissue with mesh
14 and associated foreign body giant cell reaction and
15 chronic inflammation.

16 A. Right. Okay. Exactly.

17 Q. That's what was found by the
18 pathologist at Penn, right?

19 A. Right.

20 Q. And that's consistent with a chronic
21 foreign body reaction and a chronic inflammatory
22 response, correct?

23 A. Okay.

24 Q. Is that correct?

25 A. That's correct.

1 You keep saying, I mentioned urgency more than
2 frequency; and what I keep saying is, you didn't
3 mention frequency in your report as a condition Mrs.
4 Corbet had preoperatively; is that true?

5 A. It's probably true that I didn't say
6 the word "frequency."

7 Q. In your report, you talked about the
8 extent to which complaints by Mrs. Corbet were
9 either made or documented, with various positions as
10 she went through her care after the mesh was
11 removed, right?

12 A. Yes.

13 Q. As you sit here now, am I correct,
14 you're not disputing that Mrs. Corbet has had
15 dyspareunia from after the surgery by Dr. Smith up
16 to the present? You're not disputing that, are you?

17 A. No.

18 Q. The pelvic hematoma that she had,
19 that likely resulted from the TVT procedure, right?

20 A. It's possible that that's what caused
21 it, yes.

22 Q. Based on the location of where it was
23 found on the MRI and the CT guided percutaneous
24 drainage, it's in the proximity -- direct proximity
25 to the TVT arm, isn't it?

1 A. It's in the retropubic space where
2 the TVT would have traversed.

3 Q. It's actually in the left part of
4 that space adjacent to the where the arm was,
5 correct?

6 A. Right.

7 Q. The same arm that eroded, correct?

8 A. It was on the same side as the -- as
9 the exposure.

10 Q. It's actually adjacent to that spot,
11 right?

12 A. It's on the same side as the -- the
13 hematoma and the exposure were both on her left
14 side. Whether they are correlated or connected or
15 not, I cannot say.

16 Q. Based on the description of the size
17 and location of the hematoma, it likely was adjacent
18 to and touching the mesh, right?

19 A. Possibly, yeah.

20 Q. Based on the location and size of the
21 hematoma, as described on the diagnostic studies,
22 the mesh and the placement of the mesh likely caused
23 that hematoma to form, correct?

24 A. The procedure --

25 MS. KABBASH: Objection.

1 THE WITNESS: -- of doing a
2 retropubic sling can cause a hematoma. So that
3 procedure itself could have caused the hematoma,
4 yes.

5 BY MR. SLATER:

6 Q. Most likely, that's the cause, right?

7 A. The procedure of doing the retroperitoneal
8 sling, sure, could have caused a hematoma.

9 Q. Well, most likely that is the cause,
10 right?

11 A. Moth likely.

12 Q. And they only retropubic sling she
13 had placed was the TVTTM Retropubic, right?

14 A. That's right. That's the procedure
15 that she had performed to treat her stress
16 incontinence.

17 Q. In your report, you talk about
18 treating -- and this is on Page 29 of your
19 case-specific report we've marked as Exhibit-5.

20 A. Case specific.

21 Q. Page 29, Exhibit-5. I just want to
22 ask you about something.

23 A. Sure.

24 Q. You talk about patients having mesh
25 exposure and complaining of dyspareunia, and then

1 as being beyond the scope.

2 MR. SLATER: And I'm not going to
3 stop asking it.

4 MS. KABBASH: It's your time.

5 BY MR. SLATER:

6 Q. Do you consider yourself to be an
7 expert with regard to the technical terminology of
8 heavyweight and lightweight mesh, in terms of what
9 is heavyweight and what is lightweight?

10 A. An expert?

11 Q. Yes.

12 A. I'm not a medical materials expert,
13 so no.

14 - - -

15 (Whereupon, Exhibit Fleischmann-8,
16 December 2007 E-mails, was marked for
17 identification.)

18 - - -

19 BY MR. SLATER:

20 Q. I've handed you what I've marked as
21 Exhibit-8, which is a couple e-mails from December
22 2007.

23 Do you see the bottom e-mail is an
24 e-mail from Jeff Potkul to you?

25 A. Yes.

1 bridging fibrosis is?

2 A. Yes, I've been told that scar plating
3 and fibrosis is.

4 Q. You've been told what it is by who?

5 A. Through my reading.

6 Q. Well, where did you read that?

7 A. In the medical literature.

8 Q. In connection with your work to get
9 ready to be an expert in this case, is that when you
10 learned what scar plating and bridging fibrosis was?

11 A. No, I've heard that term well before
12 I became an expert.

13 Q. What is scar plating and bridging
14 fibrosis?

15 A. It has to do with the fibrotic
16 reaction that happens when -- mostly when pore sizes
17 are too small and the bridge happens over the pores
18 where the tissue doesn't infiltrate.

19 Q. Do you agree that scar plating and
20 bridging fibrosis can cause adverse reactions?

21 A. I don't know that it has a clinical
22 significance.

23 Q. Do you agree that the clinical
24 manifestation of scar plating and bridging fibrosis
25 can include contraction, pain, erosion, extrusion

1 and exposure?

2 A. I can't agree with that, no.

3 Q. So if Ethicon says that, you disagree
4 with Ethicon?

5 MS. KABBASH: Objection.

6 THE WITNESS: I don't know what
7 Ethicon says about that. I'm just telling you that
8 I don't see how that's related to anything clinical.

9 BY MR. SLATER:

10 Q. Here is my question: If Ethicon
11 believes that scar plating and bridging fibrosis can
12 be associated with adverse events and that the
13 clinical manifestation would be contraction, pain,
14 erosion, extrusion and exposure, you would disagree
15 with that?

16 MS. KABBASH: Objection.

17 BY MR. SLATER:

18 Q. Is that what you're saying?

19 A. I'm saying I would need to see more
20 of the documentation before I respond yes or no to
21 that.

22 Q. So as you sit here now, you don't
23 know whether or not scar plating and bridging
24 fibrosis can be associated with adverse events and
25 that the clinical manifestation would be

1 contraction, pain, erosion, extrusion and exposure?

2 A. Exactly --

3 MS. KABBASH: Objection.

4 THE WITNESS: -- because you're
5 talking about something that's happening on a
6 cellular level, and I don't know how that relates to
7 a clinical outcome.

8 BY MR. SLATER:

9 Q. And you've never studied that
10 question, correct?

11 A. I read about it, but I don't see the
12 correlation in my practice or in any of the medical
13 literature that I've reviewed.

14 Q. This is my question: Have you
15 actually ever studied that question to try to form
16 an opinion on that question?

17 A. My opinion is that there's no
18 clinical significance to any kind of scarification
19 that might happen. That is a known process that
20 happens with mesh and one which we actually rely
21 upon.

22 Q. Is it your testimony that scar
23 plating and bridging fibrosis is something that you
24 rely upon in the use of the mesh?

25 A. No, scar. Scar. Fibrosis. That's

1 the natural reaction of the body to mesh.

2 Q. I'm asking about scar plating and
3 bridging fibrosis. So let me be very clear.

4 Have you ever studied the question of
5 whether or not scar plating and bridging fibrosis
6 can be associated with adverse events, the clinical
7 manifestation of which would be contraction, pain,
8 erosion, extrusion and exposure? Have you ever
9 looked at that question to form an opinion?

10 A. I haven't --

11 MS. KABBASH: Objection.

12 THE WITNESS: I haven't studied that
13 question. I can tell you, I don't see scar plating
14 or bridging fibrosis clinically in my patients.

15 BY MR. SLATER:

16 Q. Scar plating and bridging fibrosis is
17 something that would be determined by someone
18 specifically looking for it on a
19 histopathological --

20 A. Exactly. That's my point.

21 Q. So that's not something you look for,
22 right?

23 A. I can't look for. It's not something
24 I can see clinically.

25 Q. If you wanted to, you could have the

1 explanted mesh from your patients studied, right?

2 A. Sure.

3 Q. You've never done that, right?

4 A. Well, if I had explanted mesh, it
5 would be sent for pathology, sure.

6 Q. Have you ever had explanted mesh from
7 your patients studied, on a histopathological basis,
8 to determine whether there was scar plating or
9 bridging fibrosis?

10 A. Not that I've ordered. It might have
11 happened, but I've never ordered that.

12 Q. So just to be very clear so we can
13 move on, but I just want to be clear.

14 Am I correct that you have never
15 studied the question of whether scar plating and
16 bridging fibrosis can cause adverse events, the
17 clinical manifestation of which would be
18 contraction, pain, erosion, extrusion and exposure?
19 Am I correct you have not studied that specific
20 question?

21 A. I've never studied that on a
22 histopathological level.

23 Q. Did you read Dr. Klinge's report
24 about that subject?

25 A. I have, at some point, perused Dr.

1 Klinge's report. But I don't -- I can't quote from
2 it.

3 Q. Did you read any of the published
4 literature on that question?

5 A. There's not much published literature
6 on that question. It's pretty minimal.

7 Q. So is the answer you haven't?

8 A. What's out there, I have reviewed.
9 And I don't give much credence to it.

10 Q. Do you know if Ethicon gives credence
11 to that literature?

12 A. I'm not part of Ethicon, so I can't
13 say what Ethicon does.

14 Q. When Ethicon talks about the
15 complications and the risks from the TVTTM
16 Retropubic device, do you think Ethicon knows what
17 it's talking about?

18 MS. KABBASH: Objection.

19 THE WITNESS: In some ways. But
20 Ethicon is not the one that's putting the slings in.
21 We are. We are the ones that see the outcomes and
22 the clinical outcomes.

23 BY MR. SLATER:

24 Q. Do you know Peeten Wolf?
25 A. Not personally.

1 be extremely rare.

2 MR. SLATER: Move to strike from
3 "but" forward.

4 BY MR. SLATER:

5 Q. Turn to Page 26 of your report, if
6 you could.

7 You talk during your report -- in
8 your report, about degradation of mesh. Have you
9 ever studied the question of whether or not the mesh
10 in the TVTTM Retropubic degrades on any level,
11 whether a macro level or a micro level?

12 A. I've read the literature about
13 degradation. I find it's pretty scant.

14 Q. Have you ever looked at Ethicon's
15 internal documents regarding degradation of PROLENE®
16 mesh?

17 A. I've reviewed some of them in
18 preparation for this deposition, yes.

19 Q. Did the people who showed you Ethicon
20 documents show you any of the internal documents
21 that show that degradation of PROLENE® mesh occurs?
22 Did you see those documents?

23 A. I didn't find anywhere that there was
24 degradation of mesh that had occurred.

25 Q. So whatever you were provided from

1 Ethicon's documents, you weren't provided those
2 documents, were you?

3 MS. KABBASH: Objection.

4 THE WITNESS: I think if those
5 documents had existed, they might have provided them
6 to me.

7 BY MR. SLATER:

8 Q. Meaning you would expect you would
9 have been given them, if they existed, right?

10 A. Yes.

11 Q. I have a question about the TVT
12 EXACT®® -- rephrase.

13 With the TVT EXACT®®, it's the same
14 mesh, the same size mesh as with the TVTTM
15 Retropubic, and you said the difference is just the
16 insertion with the trocars, and it's inserted a
17 little bit differently?

18 A. Well, it depends. I think the TVT
19 EXACT®® is more the laser cut mesh, whereas the
20 retropubic TVT that I was using years ago was a
21 mechanical cut mesh.

22 Q. The mesh in the TVT EXACT®® is laser
23 cut?

24 A. I think so, yes.

25 Q. The TVTTM Retropubic mesh that you

1 not in relation to the sling.

2 Q. You're not -- you're not offering
3 opinions -- rephrase.

4 You're not proposing to offer expert
5 opinions regarding cytotoxicity in this case, are
6 you?

7 A. I'm not a histopathologist, so no.

8 MR. SLATER: I don't have any other
9 questions.

10 - - -

11 (Whereupon, a discussion off the
12 record occurred.)

13 - - -

14 VIDEO TECHNICIAN: The time is 2:04
15 p.m. Going off the record.

16 - - -

17 (Whereupon, a discussion off the
18 record occurred.)

19 - - -

20 VIDEO TECHNICIAN: The time is 2:08
21 p.m. We are back on the record.

22 - - -

23 EXAMINATION

24 - - -

25 BY MS. KABBASH: